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Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom

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1 Attitudes of doctors to the Committee on Safety of Medicines' (CSM) adverse drug reaction (ADR) reporting scheme were investigated in order to assess their understanding of the purposes of the scheme and to identify reasons for failing to report suspected adverse drug reactions.

2 A postal questionnaire and letter of invitation were sent to 500 doctors who were randomly selected from the 1992 Medical Directory. A reminder letter and a second copy of the questionnaire were sent to non-responders after 4 weeks.

3 284 (57%) responded to the questionnaire. Of these, 179 (63%) stated that they had previously reported an ADR to the CSM or a pharmaceutical manufacturer. 77% of general practitioners stated that they had reported one or more ADRs compared with 55% of hospital doctors.

4 Reasons for under-reporting included lack of time, lack of report forms and the misconception that absolute confidence in the diagnosis of an adverse reaction was important in the decision to send in a report.

5 An investigation of seven commonly proposed reasons for under-reporting showed that on the whole they did not apply.

6 Most doctors knew the types of reactions that the Committee on Safety of Medicines seeks reports for but only 38% knew the precise meaning of the Committee on Safety of Medicines' black triangle symbol. There also seemed to be confusion about some of the purposes of the adverse drug reaction reporting scheme.

7 The number of reporting doctors is much higher than has previously been estimated. However, there is still a significant lack of understanding about the yellow card reporting scheme and this seems to be contributing to under-reporting. Increasing the profile of the Committee on Safety of Medicines' ADR reporting scheme may improve reporting rates and the numbers of reporting doctors.

Keywords adverse drug reaction Committee on Safety of Medicines survey medical practitioners

Introduction

The reporting of suspected adverse drug reactions (ADRs) to the Committee on Safety of Medicines (CSM) is fundamental to the safety surveillance of marketed medicines. Notwithstanding the success of the 'yellow card' reporting scheme, however, only a small proportion of even severe ADRs are notified [1].

Accumulating evidence suggests that doctors' attitudes to national ADR reporting schemes are significant determinants of reporting rates [2–4]. The present survey was conducted in order to assess the attitudes of UK doctors to the CSM's yellow card scheme so as to identify reasons for under-reporting and to determine what steps might be effective in increasing reporting rates. Similar surveys, using the same questionnaire, are being conducted in other member states of the European Union.

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Methods

Attitudes of doctors to the CSM's yellow card scheme were assessed by means of a postal questionnaire. The questionnaire was based on one used previously [4] in a regional survey but modified to take into account the national basis of the current investigation and simplified to exclude irrelevant and non-contributory questions. The modified questionnaire was piloted on a non-random sample of the target population and subjected to further minor alterations before use.

A sample of 500 doctors registered in the UK was selected, at random, from the 1992 Medical Directory. All participants were sent a personally addressed letter of invitation and a questionnaire. After 4 weeks non-responders were sent a reminder letter and a second copy of the questionnaire. The questionnaire was designed to determine the attitudes of doctors to the CSM's adverse drug reaction reporting scheme, to assess their understanding of the purposes of the scheme, and to identify reasons for failing to report suspected ADRs. It also sought information about respondents' type of practice (primary health care, hospital or other), and the year of graduation. The years of graduation of non-responders were determined from the 1992 Medical Directory. All data were anonymised before analysis.

The responses to the questionnaire were analysed by producing descriptive statistics. Cross tabulations by type of practice and by whether a doctor had ever made an ADR report were also undertaken. The questionnaire was designed in such a way that respondents should have answered each part of each question. However, where respondents had answered individual questions incompletely they were removed from the analysis of that question only.

Results

Questionnaires were returned from 284 out of the 500 doctors contacted, giving an overall response rate of 57%. Responders consisted of similar proportions of hospital doctors (48%) and general practitioners (42%) with less than 10% from other areas of practice. The median year of graduation was 1975 for responders and 1979 for non-responders.

Question 1 sought information about whether respondents had ever reported an ADR to either the CSM or the manufacturer. Table 1 shows that of the doctors who replied, 63% had sent in an ADR report either to the CSM or to a pharmaceutical manufacturer. Ninety-one (77%) general practitioners had sent in an ADR report, compared with 55% hospital doctors and 44% doctors from other areas of practice. Only one doctor left this question blank.

Question 2 asked what factors were important to respondents in deciding whether to report an ADR. Seriousness or unusualness of the reaction, or the involvement of a new product, were stated as important in the decision to report by over 85% (Table 2). There seemed to be no difference between those who had, and had not, reported an ADR or between those in different areas of practice. Half, however, said that their degree of confidence in the diagnosis of the ADR was important with hospital doctors (59%) being more likely to regard this as a significant component when compared with general practitioners (43%).

Question 3 sought information about factors that might discourage ADR reporting (Table 3). The first two items were designed to ascertain whether reporting forms were available when needed, and whether the disclosure of confidential information inhibited reporting. Whilst the former appeared to be a significant deterrent, the latter did not. The remaining seven items in question 3 sought to determine whether Inman's 'seven deadly sins' [5] inhibited reporting. These comprise *ignorance* ('I am unsure how to report and ADR'), *diffidence* ('I may appear foolish about reporting a suspected ADR'), *fear* ('I may expose myself to legal liability by reporting an ADR'), *lethargy* ('I am too busy to report ADRs'), *guilt* ('I am reluctant to admit I may have caused harm'), *ambition* ('I would rather collect cases and publish them') and

Table 1 Number of doctors who had sent an adverse drug reaction report (yellow card)

	Yes	*No*	*Missing*
Doctor had sent an ADR report	178 (62.7%)	105 (37.0%)	1 (0.3%)
Doctor had sent an ADR report to the CSM	171 (60.2%)	110 (38.7%)	3 (1.1%)
Doctor had sent an ADR report to a pharmaceutical manufacturer	48 (16.9%)	198 (69.7%)	38 (13.4%)

Percentages are of total number of forms received (284).

Table 2 Factors important in a doctor's decision to send in an adverse drug reaction report

	Important	*Not sure*	*Unimportant*
Seriousness of the reaction	247 (95%)	6 (2%)	8 (3%)
Unusual reaction	232 (89%)	23 (9%)	6 (2%)
Reaction to a new product	237 (91%)	17 (7%)	7 (3%)
Degree of confidence in the diagnosis of the ADR	129 (49%)	80 (31%)	52 (20%)

Percentages are of row totals. Responders removed for leaving part of question blank: 23 (8%). Due to rounding percentages may add up to more than 100.

Table 3 Issues that discourage ADR reports

	Yes	*Not sure*	*No*
Report forms are not available when needed	55 (21%)	14 (5%)	191 (74%)
Doctor does not like reporting confidential information	7 (3%)	12 (5%)	241 (93%)
*Doctor unsure how to report an ADR	7 (3%)	9 (4%)	244 (94%)
*Doctor fears he/she may appear foolish about reporting a suspected reaction	20 (8%)	25 (10%)	215 (83%)
*Doctor fears he/she may be exposed to legal liability by reporting a reaction	2 (1%)	36 (14%)	222 (85%)
*Doctor is too busy to send an ADR report	54 (21%)	45 (17%)	161 (62%)
*Doctor is reluctant to admit he/she may have caused a patient harm	13 (5%)	23 (9%)	224 (86%)
*Doctor would rather collect and publish personally	2 (1%)	3 (1%)	255 (98%)
*Doctor believes only safe drugs are marketed	14 (5%)	19 (7%)	227 (87%)

*Questions to test Inman's seven deadly sins.
Percentages are of row totals. Responders removed for leaving part of question blank: 24 (9%). Due to rounding percentages may add up to more than 100.

complacency ('only safe drugs are marketed'). Of these only lethargy appeared to inhibit, significantly, ADR reporting.

In question 4 respondents were asked about the significance of the black triangle (▼) that appears on data sheets, in MIMS, the British National Formulary and advertising literature for new products. The majority (64%) knew that the symbol signified that all suspected reactions to the product should be reported although a higher proportion of general practitioners responded correctly (77%) compared with hospital doctors (55%). Only 48% of respondents knew that the black triangle indicated a new drug and overall only 39% answered both parts of the question correctly. Again, general practitioners were better informed than hospital doctors with 46% and 35% (respectively) answering both parts correctly.

Question 5 sought respondents' views on the types of problems for which the CSM seeks ADR reports (Table 4). Over 80% of doctors gave the correct response for most parts of this question. However, 47% of doctors thought that the Committee requested reports for all suspected reactions to established products. More reporters (39%) than non-reporters (27%), and more general practitioners (43%) than hospital doctors (30%), knew the correct answer to this question. A small majority (59%) correctly indicated that all reactions to vaccines should be reported.

Question 6 asked respondents to indicate what they regarded as the purposes of the CSM's reporting scheme (Table 5). Although most respondents recognised that the scheme was intended to identify previously unrecognised reactions to drugs, there was a lesser appreciation that it was also able to identify predisposing factors, and characterise reactions.

Table 4 Doctors' opinions of the types of problems for which the Committee on Safety of Medicines seeks adverse drug reaction reports

	Yes	*Not sure*	*No*
Serious suspected reactions to established products	248 (95%)	9 (3%)	4 (2%)
All suspected reactions to established products	122 (47%)	49 (19%)	90 (35%)
All suspected reactions to new products	253 (97%)	7 (3%)	1 (0.4%)
Only serious suspected reactions to new products	15 (6%)	18 (7%)	228 (87%)
Only proven adverse reactions	7 (3%)	28 (11%)	226 (87%)
Suspected teratogenic effects	237 (91%)	16 (6%)	8 (3%)
All suspected adverse reactions to vaccines	155 (59%)	68 (26%)	38 (15%)

Percentages are of row totals. Responders removed for leaving part of question blank: 23 (8%). Due to rounding percentages may add up to more than 100.

Table 5 Doctors' views on the purposes of the Committee on Safety of Medicines' reporting scheme

	Yes	*Not sure*	*No*
To enable safe drugs to be identified	161 (64%)	37 (15%)	52 (21%)
To measure the incidence of all adverse reactions to drugs	170 (68%)	24 (10%)	56 (22%)
To identify factors which might predispose to ADRs	183 (73%)	53 (21%)	14 (6%)
To identify previously unrecognised reactions to drugs	244 (98%)	6 (2%)	0
To obtain information about the characteristics of particular reactions	178 (71%)	55 (22%)	17 (7%)

Percentages are of row totals. Responders removed for leaving part of question blank: 34 (12.0%).

Discussion

There has, previously, been only one attempt to ascertain the attitudes of the British medical profession to the CSM's 'yellow card scheme' [4]. That study, conducted amongst doctors practising in circumscribed areas in the north-east of England, was designed to compare attitudes amongst doctors in Health Authorities with divergent reporting rates. By contrast, the present investigation was designed as a national survey to assess attitudes to, and understanding of, the UK spontaneous reporting scheme by doctors generally.

The overall response rate (57%) was disappointing. The response rate was particularly poor for those graduating after 1987 and this probably reflects the difficulty in locating mobile trainees, either in hospitals or in general practice, from addresses in the Medical Directory. The difference in the median year of graduation of responders (1975) and non-responders (1979) is a reflection of this. The response rate for doctors graduating in the 1960s was correspondingly higher. Notwithstanding the problems that arise in interpreting the responses to the present questionnaire, a number of important points emerge.

First, 63% of responders claimed to have reported an ADR to either the CSM (via a yellow card) or to a manufacturer (who has a statutory obligation to pass the information to the Medicines Control Agency). This is substantially in excess of a previous estimate (16%) [6] of the proportion of doctors who have 'ever' submitted a report of an ADR. Even if none of the non-responders had 'ever' reported an ADR, the proportion of reporters amongst the UK medical profession (37%) is more than double that of the only previous estimate. The higher proportion of general practitioners who claimed to have sent ADR reports to the CSM, when compared with hospital doctors, is concordant with the observation that more than two-thirds of the total number of yellow cards received come from general practitioners. The smaller proportion of doctors who claim to report directly to pharmaceutical companies, compared with those reporting directly to the CSM, is again consistent with the fact that 85–90% of all yellow cards are derived directly from the medical profession.

Second, responders generally had a good appreciation of the objectives of the 'yellow card' scheme and were positive about its importance in monitoring the safety of marketed medicines. Overall, however, doctors in general practice were more aware of the criteria for reporting ADRs than their colleagues in hospital practice. This confirms the results of the previous attitudinal survey of doctors in the UK [4]. It emphasises the need to develop a more robust ADR reporting culture amongst hospital doctors particularly in view of the fact that patients with the most severe ADRs are likely to present to hospital.

Third, the survey failed to substantiate that six of the seven 'traditional' reasons [5] given for failing to report ADRs are, in fact, deterrents to reporting. There was however a clear indication that a heavy work-load deterred ADR reporting (Table 3) amongst both general practitioners (27%) and hospital doctors (17%). This, again, is concordant with the previous UK study [4].

Fourthly, the survey elucidated at least some of the factors that inhibit yellow card reporting. Lack of confidence in an iatrogenic diagnosis, especially amongst hospital doctors, appears to deter reporting (Table 2). The CSM wishes to receive reports of *suspected* ADRs as well as *proven* ones. Unavailability of report forms (Table 3) apparently limits reporting by doctors generally though these are interleaved in the British National Formulary, the Data Sheet Compendium, the OTC directory, MIMS and FP10 prescription pads. However the gradual disappearance of the last of these, with increasing use of computerised prescribing stationery, may have had a detrimental effect on reporting by general practitioners. Although almost all respondents appreciated that the yellow card scheme acts as an 'early warning system' (Table 5) they were less aware of its other roles. Finally, the precise meaning of the black triangle (▼) symbol that appears in prescribing literature and promotional material was not known by over half of all responders.

In conclusion, whilst the medical profession is generally supportive of the CSM's yellow card scheme there are a number of areas of misunderstanding which may contribute to under-reporting. Most important of all, however, is the need to ensure that an ADR reporting culture pervades the profession as a whole.

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